K011319

JUL 2 0 2001

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ENDOSCOPY

SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Classification Name:	Smooth or Threaded Metallic Bone Fixation Fasteners: 21 CFR §888.3040, Class II
Common and Usual Name:	Threaded Fixation Pin (87 JDW)
Proprietary Name:	Stryker Titanium Cross-Screw System

Predicate Device

Medicine Lodge, Inc. (MLI) Cross Pin (#K961920) currently marketed by Innovasive/Mitek Products (Westwood, MA).

Summary

This summary of 510(k) safety and effectiveness is being submitted in accordance with requirements of SMDA 1990.

The Stryker Titanium Cross-Screw System is intended for use in the surgical reconstruction of cruciate ligament deficient knees to provide cross pin femoral fixation of the various soft tissue autografts and allografts. The cross pin fixation technique is a common method in orthopedic surgery, and has been well published in professional journals[1,2,3]. The Stryker Titanium Cross-Screw System is best represented by the technique described by James J. Lam et al[3]. The Stryker Titanium Cross-Screw is inserted over a rigid guide wire through the apex of the soft tissue graft for femoral fixation.

The Stryker Titanium Cross-Screw, which is the implant component of the system, will be provided sterile for single-use applications (ASTM 4169). This device will be sterilized by Gamma irradiation (EN 552) or Ethylene oxide (EN550) and validated to a sterility assurance level (SAL) of 10^{-6}. The device is biocompatible per ISO-10993 and G95-1. The Stryker Titanium Cross-Screw System is equivalent in intended use, safety, and efficacy to the MLI predicate device. The material of construction (Ti-6Al-4V ELI per ASTM F136) and its overall design are equivalent to the predicate device.

The Stryker Titanium Cross-Screw System does not raise new issues when compared to the currently marketed predicate device. Therefore, it is considered substantially equivalent to the MLI Cross Pin and system.

Contact:

Ryan Yearsley
Sr. Design Engineer
Stryker Endoscopy
2590 Walsh Ave.
Santa Clara, CA 95051
(408) 567-9100 x.2583

Date: April 27, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Mr. Ryan Yearsley
Senior Design Engineer
Stryker Endoscopy
2590 Walsh Avenue
Santa Clara, California 95051

Re: K011319
Trade Name: Stryker Titanium Cross-Screw System
Regulation Number: 21 CFR 888.3040
Regulatory Class: II
Product Code: JDW
Dated: April 27, 2001
Received: May 1, 2001

Dear Mr. Yearsley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

April 27, 2001

510(k) Number if known: K011319

INDICATION FOR USE:

Intended for use in the surgical reconstruction of cruciate ligament deficient knees to provide cross pin femoral fixation of the various soft tissue autografts and allografts.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011319